K083021

APPENDIX I: 510(K) Summary

OCT 29 2008

SUBMITTER:

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DATE PREPARED:

October 8, 2008

DEVICE TRADE NAME:

Apex HP M Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator

COMMON NAME:

Hollow Fiber Oxygenator

CLASSIFICATION NAME:

Cardiopulmonary Bypass Oxygenator

LEGALLY UNMODIFIED DEVICE:

Apex M Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator (K020997)

PREDICATE DEVICE:

Dideco D 903 Avant 2 Ph.I.S.I.O Adult Hollow Fiber Oxygenator (K020351)

DEVICE DESCRIPTION:

The Apex HP M Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator is a cardiopulmonary bypass blood oxygenator with an integral heat exchanger.

INDICATION FOR USE:

The Apex HP M Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

TECHNOLOGICAL CHARACTERISTICS:

The Apex HP M Ph.I.S.I.O Adult Hollow Fiber Membrane Oxygenator is identical in design, materials, operating principles and control mechanisms to the Apex M Adult Hollow Fiber Membrane Oxygenator predicate device. The only modifications made to the device consist of an overall reduction in the size of the device, optimization of the heat exchanger water path, updating of the instructions for use reflecting this modification and change in Ph.I.S.I.O. trade name. The fundamental scientific technology is unchanged from the predicate device. The coating is identical to the phosphorylcholine coating used on the Apex M Ph.I.S.I.O. unmodified and D 903 Avant 2 Ph.I.S.I.O. predicate device. The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

NONCLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1:1997 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials. As no new materials are used in the APEX HP M Ph.I.S.I.O. oxygenator compared to the unmodified and predicate device as a result of the modifications, this 510(k) cross references biocompatibility data previously submitted. Tests were performed on devices accelerated aged to an equivalent of three years real time aging. Sterility, pyrogenicity, EO residuals and package integrity testing were also conducted. The results of testing met established specifications.

IN VITRO TEST RESULTS:

In vitro testing was carried out in accordance with the requirements of ISO 7199 and the Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff November 13, 2000 to provide the data necessary to demonstrate compliance of the unmodified device with safety and effectiveness requirements. The Apex HP M Ph.I.S.I.O. Oxygenator was aged to 3 years and tested for gas transfer characteristics, pressure drop, plasma leakage data, operating blood volume, heat exchanger performance evaluation, hemolysis/cell depletion, mechanical integrity and leaking test. The results of these tests met established specifications. For comparative purposes all tests, where applicable, were carried out on sterilized aged devices comparing the Apex HP M Ph.I.S.I.O. and the Apex M Ph.I.S.I.O. unmodified device. In addition, the functional and biocompatibility parameters exhibited by Apex M Ph.I.S.I.O. apply to Apex HP M Ph.I.S.I.O.

CONCLUSION:

Test results show that the Apex HP M Ph.I.S.I.O. performs in a manner substantially equivalent to the unmodified device. Biocompatibility studies demonstrate that the device is biocompatible according to its intended use. Additional testing has also demonstrated the effectiveness of production techniques to assure that Apex HP M Ph.I.S.I.O. is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2008

Sorin Group Italia S.r.l.
c/o Mr. Barry Sall
Principal Consultant
200 West Street
Waltham, MA 02451

Re: K083021
Apex HP M Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Oxygenator, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: October 8, 2008
Received: October 9, 2008

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K083021

Device Name: Apex HP M Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator
Indications for Use:

The Apex HP M Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

Prescription Use __X___
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use_____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083021